IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
MINNEAPOLIS DIVISION

HELEN SALAS,	§	
	§	
PLAINTIFF,	§	CIVIL ACTION NO. _0:21-cv-2631_____
	§	
VS.	§	
	§	**JURY DEMANDED**
TORAX MEDICAL, INC., AND ETHICON, INC.	§	
	§	
	§	
DEFENDANTS.	§	

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff Helen Salas files this, her Original Complaint, against Defendants Torax Medical, Inc. and Ethicon Inc., and respectfully states follows:

I.

PRELIMINARY STATEMENT

Defendant's Torax Medical, Inc. and Ethicon, Inc. manufactured a defective medical device such that Plaintiff suffered significant injury. Here, a defectively manufactured LINX was surgically implanted in Plaintiff to control her gastroesophageal reflux disease (GERD). After the LINX was implanted in Plaintiff, Defendants became aware of the manufacturing defect in Plaintiff's LINX. Defendants recalled Plaintiff's LINX as well as numerous other LINX devices in the United States and European Union. Moreover, Defendants admit that Plaintiff's LINX was defectively manufactured.

Here, Plaintiff seeks to vindicate her rights at law for having to experience a severe recurrence of her GERD symptoms and undergo another invasive surgery to remove the defective LINX.

II.

PARTIES

1. Plaintiff Helen Salas is a resident of the State of California.

2. Defendant Torax Medical, Inc. (Torax) is a Delaware corporation with its headquarters and principal place of business in Shoreview, Minnesota. Torax may be served with process through its registered agent, The Corporation Trust Company at 1209 Orange St., Wilmington, Delaware 19801, or wherever it may be found. While headquartered in Minnesota, Torax's medical devices, including the LINX, are distributed, marketed, sold, and used on medical patients in all fifty United States, including Minnesota, and the European Union. Therefore, Torax is subject to personal jurisdiction in the State of Minnesota.

3. Ethicon, Inc. (Ethicon) is a New Jersey corporation with its headquarters and principal place of business in the State of New Jersey. Ethicon may be served with process through its registered agent Johnson & Johnson, at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-0000, or its president Nefertiti Green, at Johnson & Johnson, Rt. 22 West, Somerville, New Jersey 08876, or wherever she may be found. While headquartered in New Jersey, Ethicon's medical devices, including the LINX, are distributed, marketed, sold, and used on medical patients in all fifty United States, including Minnesota, and the European Union. Therefore, Ethicon is subject to personal jurisdiction in the State of Minnesota.

III.

JURISDICTION & VENUE

4. This Court has jurisdiction over this proceeding pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds $75,000.00.

5. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b)(1) and (2).

IV.

FACTS APPLICABLE TO ALL COUNTS

6. This case arises from the defective manufacturing by Defendants Torax and Ethicon of a medical device known as the "LINX Reflux Management System" ("LINX"). LINX is a titanium bead-and-wire ring surgically implanted around a patient's lower esophageal sphincter (LES) to augment the LES and prevent acid reflux. These devices can only be implanted surgically, and they are used to treat gastroesophageal reflux disease (GERD) which is a disease predominately suffered by the elderly.

 [1]

[1] https://www.jnj.com/innovation/johnson-johnson-medical-innovations-reshaping-future-surgery

7. The LINX required pre-market approval by the Food & Drug Administration prior to it being placed in the stream of commerce and used on patients in the United States and the European Union. Specifically, in December 2010, Defendant Torax applied for this pre-market approval, including its manufacturing process, and this approval was granted on March 22, 2012. The LINX is considered a "restricted" device, meaning it is subject to numerous FDA regulations regarding the manufacture, distribution, and marketing of the device.

8. Defendant Ethicon, Inc. (Ethicon) is the parent-corporation for Defendant Torax and participated in the manufacture, distribution, and post-market surveillance of the LINX.

9. On May 31, 2018, Defendant Torax initiated a recall of numerous LINX due to "an out of specification condition" which would allow "a bead component to separate from an adjacent wire link."[2] This means that the LINX device, normally a continuous loop, would become discontinuous and open due a defect resulting from improper manufacture.

This recall, classified as a Class 2 recall, is considered by the FDA as "a method of removing…products that are in violation of laws" administered by the FDA. FDA records show that there were 9,131 LINX devices in the stream of commerce as of May 2018.

[2] *See* Exhibit "A" – Notice of Recall

10. A 15-bead LINX was surgically implanted in Plaintiff on October 23, 2016. This LINX was subject to the recall described in ¶ 6.

11. Plaintiff the defective LINX has not been removed.

12. Plaintiff alleges that Defendants Torax and Ethicon manufactured the LINX which was implanted in Plaintiff and subsequently failed due to a manufacturing defect. Plaintiff alleges that Defendants Torax and Ethicon placed Plaintiff's LINX device into the stream of commerce. Plaintiff alleges that Defendants Torax and Ethicon are corporations who regularly design, test, assembly, manufacture, sell, and distribute medical devices intended for human use.

V.

CAUSES OF ACTION

A. Manufacturing Defect As to Defendant Torax – Strict Liability

13. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in strict liability for product defect, from Defendant Torax for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

14. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA and provided by Defendant Torax for its pre-market approval. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

15. Specifically, Defendant Torax was required to manufacture the defective LINX device according to Federal Regulations, including but not limited to the following, and failed to do so in:

- 21 CFR 820.5 – failure to establish and adhere to a quality system to prevent the manufacture of defective LINX;
- 21 CFR 820.20 – failure to adhere to approved quality system procedures;
- 21 CFR 820.70(a),(g), (h), (i) – failure to control production processes to ensure device conformance with specifications;
- 21 CFR 820.72 – failure to inspect, measure, and test manufacturing equipment and materials such that the LINX was defectively manufactured;
- 21 CFR 820.75 – failure to adhere to process validation and implement process validation such that the LINX was placed in the stream of commerce in a defective condition;
- 21 CFR 820.90 – failure to prevent non-conforming product, e.g. Plaintiff's LINX, from entering the stream of commerce in a defective condition;
- 21 CFR 820.100 – failure to implement corrective processes and preventative actions due to nonconformities.

16. As a result of Defendant Torax's violations of federal regulation, approved-manufacturing process, and manufacturing standard of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Torax, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

17. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

B. Manufacturing Defect As to Defendant Torax – Negligence

18. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from Defendant Torax for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

19. Specifically, Defendant Torax owed Plaintiff a duty of ordinary care as would a reasonable and prudent manufacturer of medical devices to manufacture the LINX such that it would be safe for its intended use. Plaintiff alleges that Defendant Torax failed to use ordinary care by various acts and omissions, which constitute negligence, in at least the following ways:

- Failure to manufacture the LINX consistent with approved manufacturing standards such that it was defective and unreasonably dangerous for its intended use;
- Failure to manufacture the LINX consistent with approved design such that it was defective and unreasonably dangerous for its intended use;
- Failure to test and inspect the device prior to placing it in the stream of commerce in a defective and unreasonably dangerous condition; and
- Failure to prevent the defectively manufactured device from entering the stream of commerce in a defective and unreasonably dangerous condition.

20. As a result of Defendant Torax's breach of its duty of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Torax, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

21. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

C. Manufacturing Defect As to Defendant Torax – Negligence Per Se

22. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in negligence per se, from Defendant Torax for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

23. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA and provided by Defendant Torax for its pre-market approval. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

24. Specifically, Defendant Torax was required to manufacture the defective LINX device according to Federal Regulations, including but not limited to the following, and failed to do so in:

- 21 CFR 820.5 – failure to establish and adhere to a quality system to prevent the manufacture of defective LINX;
- 21 CFR 820.20 – failure to adhere to approved quality system procedures;
- 21 CFR 820.70(a),(g), (h), (i) – failure to control production processes to ensure device conformance with specifications;

- 21 CFR 820.72 – failure to inspect, measure, and test manufacturing equipment and materials such that the LINX was defectively manufactured;
- 21 CFR 820.75 – failure to adhere to process validation and implement process validation such that the LINX was placed in the stream of commerce in a defective condition;
- 21 CFR 820.90 – failure to prevent non-conforming product, e.g. Plaintiff's LINX, from entering the stream of commerce in a defective condition;
- 21 CFR 820.100 – failure to implement corrective processes and preventative actions due to nonconformities.

25. These violations constitute negligence per se.

26. As a result of Defendant Torax's violations of federal regulation, approved-manufacturing process, and manufacturing standard of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Torax, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

27. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

D. <u>Manufacturing Defect As to Defendant Ethicon – Strict Liability</u>

28. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in strict liability for product defect, from Defendant Ethicon for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

29. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

30. Specifically, Defendant Ethicon was required to manufacture the defective LINX device according to Federal Regulations, including but not limited to the following, and failed to do so in:

- 21 CFR 820.5 – failure to establish and adhere to a quality system to prevent the manufacture of defective LINX;
- 21 CFR 820.20 – failure to adhere to approved quality system procedures;
- 21 CFR 820.70(a),(g), (h), (i) – failure to control production processes to ensure device conformance with specifications;
- 21 CFR 820.72 – failure to inspect, measure, and test manufacturing equipment and materials such that the LINX was defectively manufactured;
- 21 CFR 820.75 – failure to adhere to process validation and implement process validation such that the LINX was placed in the stream of commerce in a defective condition;
- 21 CFR 820.90 – failure to prevent non-conforming product, e.g. Plaintiff's LINX, from entering the stream of commerce in a defective condition;

- 21 CFR 820.100 – failure to implement corrective processes and preventative actions due to nonconformities.

31. As a result of Defendant Ethicon's violations of federal regulation, approved-manufacturing process, and manufacturing standard of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Ethicon, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

32. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

E. Manufacturing Defect As to Defendant Ethicon – Negligence

33. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from Defendant Ethicon for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

34. Specifically, Defendant Ethicon owed Plaintiff a duty of ordinary care as would a reasonable and prudent manufacturer of medical devices to manufacture the LINX such that it would be safe for its intended use. Plaintiff alleges that Defendant Ethicon failed to use ordinary care by various acts and omissions, which constitute negligence, in at least the following ways:

- Failure to manufacture the LINX consistent with approved manufacturing standards such that it was defective and unreasonably dangerous for its intended use;
- Failure to manufacture the LINX consistent with approved design such that it was defective and unreasonably dangerous for its intended use;

- Failure to test and inspect the device prior to placing it in the stream of commerce in a defective and unreasonably dangerous condition; and
- Failure to prevent the defectively manufactured device from entering the stream of commerce in a defective and unreasonably dangerous condition.

35. As a result of Defendant Ethicon's breach of its duty of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Ethicon, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

36. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

F. Manufacturing Defect As to Defendant Ethicon – Negligence Per Se

37. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in negligence per se, from Defendant Ethicon for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

38. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

39. Specifically, Defendant Ethicon was required to manufacture the defective LINX device according to Federal Regulations, including but not limited to the following, and failed to do so in:

- 21 CFR 820.5 – failure to establish and adhere to a quality system to prevent the manufacture of defective LINX;
- 21 CFR 820.20 – failure to adhere to approved quality system procedures;
- 21 CFR 820.70(a),(g), (h), (i) – failure to control production processes to ensure device conformance with specifications;
- 21 CFR 820.72 – failure to inspect, measure, and test manufacturing equipment and materials such that the LINX was defectively manufactured;
- 21 CFR 820.75 – failure to adhere to process validation and implement process validation such that the LINX was placed in the stream of commerce in a defective condition;
- 21 CFR 820.90 – failure to prevent non-conforming product, e.g. Plaintiff's LINX, from entering the stream of commerce in a defective condition;
- 21 CFR 820.100 – failure to implement corrective processes and preventative actions due to nonconformities.

40. These violations constitute negligence per se.

41. As a result of Defendant Ethicon's violations of federal regulation, approved-manufacturing process, and manufacturing standard of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Ethicon, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

42. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

VI.

DAMAGES

43. Plaintiff suffered, as a proximate and direct result of the wrongful actions and/or omissions of the Defendants in this matter, each of the following damages:

A. Reasonable medical care and expenses in the past. These expenses were incurred by the Plaintiff for the necessary care and treatment of the injuries resulting from the manufacturing defect alleged and such charges are reasonable and were usual and customary charges for such services;

B. Reasonable and necessary medical care and expenses which will in all reasonable probability be incurred in the future;

C. Physical pain and suffering in the past;

D. Physical pain and suffering which will in all reasonable probability be suffered in the future;

E. Mental anguish sustained in the past;

F. Mental anguish that, in reasonable probability, Plaintiff will sustain in the future;

G. Physical impairment in the past;

H. Physical impairment which, in all reasonable probability, will be suffered in the future;

I. Disfigurement; and

J. Costs of Court.

VI.

REQUEST FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff makes his demand for trial by jury on all issues so triable.

VII.

PRAYER

Plaintiff request that the Court award her the following relief against the Defendants above as may be appropriate:

(1) A Judgment awarding actual, compensatory, damages in the amount in excess of 75,000.00;

(2) Costs of court;

(3) Pre- and post-judgment interest at the highest legal rate allowed by law from the earliest time allowed by law; and

(4) All other relief to which Plaintiff is justly entitled.

Dated: December 8, 2021

Respectfully submitted,

MESHBESHER & SPENCE

/s/ Ashleigh E. Raso

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